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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/765,568

01/28/2004

Esther H. Chang

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8131

6449

7590

08/28/2006

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EXAMINER

HALVORSON, MARK

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/765,568

Applicant(s)

CHANG ET AL.

Examiner

Mark Halvorson

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

SPECIES ELECTION

1. This application contains claims directed to the following patentably distinct species of the claimed invention.

The invention is subject to election of at least one of the disclosed species.

Claims 5-7 are drawn to methods using multiple compounds that fails the Harnisch test. In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group share a substantial structural feature disclosed as being essential to that utility.

Claim 5 is a generic claim which include a Markush-type plurality of alternatively usable substances or members. A Markush-type claim can include independent and distinct inventions. In this case these different molecular entities are considered to be structurally, chemically and biologically independent because each is represented by a unique structural feature.

(i) Claims 5 is generic to a plurality of disclosed patentably distinct inventions of one therapeutic agents wherein there are (a) **one therapeutic agents** or (b) **more than one therapeutic agents**.

(i)(a). Inventions (a) and (b) above are further subject to restriction because claims 5 and 6 are generic to a plurality of disclosed patentably distinct inventions comprising the method of the instant invention whereby the therapeutic agent comprises: (I) a **chemotherapeutic agent**; (II) a **radiotherapeutic agent**; or (III) a **nucleic acid**.

(i)(a)(III). Invention III above is further subject to restriction because claim 6 is generic to a plurality of disclosed patentably distinct inventions comprising the method of the instant invention whereby the nucleic acid comprises a DNA molecule which

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encodes (A) a **wild type p53 molecule**, (B) an **RB molecule**, (C) an **RB94 molecule**, (D) an **apoptin** or (E) an **antisense HER-2**.

If Applicant selects more than one therapeutic agent Applicant must identify the combination of therapeutic agents to be examined.

Applicant is reminded that the selected combination must have support in the specification.

The election is further subject to election of at least one of the disclosed species.

Claims 8-12 are drawn to methods using multiple compounds that fails the Harnisch test. In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group share a substantial structural feature disclosed as being essential to that utility.

Claim 8 is a generic claim which include a Markush-type plurality of alternatively usable substances or members. A Markush-type claim can include independent and distinct inventions. In this case these different molecular entities are considered to be structurally, chemically and biologically independent because each is represented by a unique structural feature.

(ii) Claims 8 is generic to a plurality of disclosed patentably distinct species of ligands wherein the ligands comprise (a) **transferrin** (b) **folate** or (c) an **antibody or antibody fragment**.

(ii)(c). Invention (c) above is further subject to restriction because claim 8 is generic to a plurality of disclosed patentably distinct inventions comprising the method of the instant invention whereby the antibody or antibody fragment comprises: (I) a **an anti-transferrin antibody**; or (II) **an anti-HER-2 antibody**;

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

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is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.


Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Halvorson, PhD whose telephone number is (571) 272-6539. The examiner can normally be reached on Monday through Friday from 8:30am to 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Mark Halvorson, PhD
Patent Examiner
571-272-6539


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER